

# Notice of Allowability

Application No.

09/937,521

Examiner

Nashaat T. Nashed, Ph. D.

Applicant(s)

ITO, MAKOTO

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed after final rejection on July 23, 2004.
2. ☐ The allowed claim(s) is/are 1-13 and 20.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

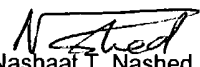
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
Nashaat T. Nashed, Ph. D.  
Primary Examiner  
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The after-final amendment filed July 23, 2004 has been entered. Accordingly, claims 1, 3, 6, 10-13, and 20 have been amended and claims 14-19 and 21 have been cancelled.

Claims 1-13 and 20 are pending and under consideration.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristi Ruppert on August 11, 2004, and Craig A. McRobbie on August 13, 2004.

The application has been amended as follows:

- Claim 1. An isolated nucleic acid comprising a nucleotide sequence selected from the group consisting of:
- (A) a nucleotide sequence encoding a polypeptide having the amino acid sequence of SEQ ID NO: 14, wherein the polypeptide possesses a ceramidase activity;
  - (B) a nucleotide sequence comprising SEQ ID NO: 15, wherein said nucleotide sequence encodes a polypeptide possessing a ceramidase activity; and
  - (C) a nucleotide sequence which hybridizes to the complement of the nucleotide sequence of SEQ ID NO: 15 under stringent conditions, wherein said stringent conditions comprise 7% PEG 6000 containing 10% SDS solution at 60 °C, and washing three times with 2XSSC containing 0.1% SDS for 15 minutes at 60 °C, wherein said nucleotide sequence encodes a polypeptide having activity of hydrolyzing any one of substances selected from the group consisting of (i) N-Lauroylsphingosine, (ii) N-Palmitoylsphingosine, (iii) N-Stearoylsphingosine, (iv) N-Palmitoylsphinganine, (v) N-Stearoylsphinganine, and (vi) 12 -((N-(7-nitrobenz-2 -oxa-1, 3-diazol-4-yl)amino)dodecanoyl)sphingosine. ;and
  - ~~(D) a nucleotide sequence different from the nucleotide sequence of (C) due to degeneracy of the genetic code, wherein said nucleotide sequence encodes a polypeptide having activity of hydrolyzing any one of the substances selected from the group consisting of (i) N-Lauroylsphingosine, (ii) N-Palmitoylsphingosine, (iii) N-Stearoylsphingosine, (iv) N-Palmitoylsphinganine, (v) N-Stearoylsphinganine, and (vi) 12 ((N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyl)sphingosine.~~

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- Claim 2. The nucleic acid according to claim 1, wherein the ceramidase activity of the polypeptide is detected by the following steps:  
(a) incubating an expression product in a reaction mixture comprising 550 pmol of 12 -((N-( 7-nitrobenz-2 -oxa-1, 3-diazol-4-yl)amino)dodecanoyl)sphingosine and 1.0%(W/V) sodium cholate in 20  $\mu$ l of 25 mM Tris-hydrochloric acid buffer, pH 7.5, (~~pH 7.5~~) at 37 °C for 30 minutes; and  
(b) detecting the formation of a 12-(N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoic ~~dodecanoyl~~ acid in the reaction.
- Claim 3. The nucleic acid according to claim 1 or 2, wherein the polypeptide exhibits at least the following characteristics:  
(i) action of hydrolyzing ceramide to generate sphingoid and a fatty acid;  
(ii) substrate specificity of hydrolyzing N-acylsphingosine, but not acting on galactosylceramide, sulfatide, Galb1-3GalNAcb1-4(NeuAca2-3)Galb1-4Glc b1-1'Cer (GM1a), and sphingomyelin;  
(iii) optimum pH of from 7.0 to 8.0; and  
(iv) ~~wherein~~ incubation in 20 mM Tris-hydrochloric acid buffer, pH 7.5, (~~pH 7.5~~) containing 0.1% polidocanol at 37 °C for 24 hours does not decrease activity of said polypeptide, whereas incubation in 20 mM Tris-hydrochloric acid buffer, pH 7.5, (~~pH 7.5~~) containing 0.1% polidocanol at 60 °C for 1 hour decreases activity of said polypeptide to about 30%.
- Claim 7. A method for producing a polypeptide possessing a ceramidase activity, comprising the steps of culturing the transformed cell ~~transformant~~ of claim 6 under conditions appropriate for expression of the polypeptide, and collecting a polypeptide possessing a ceramidase activity from the resulting culture.
- Claim 10 The polypeptide according to claim 8 or 9, wherein the ceramidase activity is detected by the following steps:  
(a) incubating an expression product in a reaction mixture comprising 550 pmol of 12 -((N-( 7-nitrobenz-2 -oxa-1, 3-diazol-4-yl)amino)dodecanoyl)sphingosine and 1.0%(W/V) sodium cholate in 20  $\mu$ l of 25 mM Tris-hydrochloric acid buffer, pH 7.5, (~~pH 7.5~~) at 37 °C for 30 minutes; and  
(b) detecting the formation of a 12-(N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoic ~~dodecanoyl~~ acid in the reaction.

Claims 1-13 and 20 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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